5.3 510(k) Summary Statement (21 CFR 807.92)

Submitter:	American Medical Systems (AMS) 10700 Bren Road West Minnetonka, MN 55343
Owner/Operator:	American Medical Systems, Inc. 10700 Bren Road West Minnetonka, MN 55434-USA
Manufacturing Sites:	American Medical Systems, Inc. 10700 Bren Road West Minnetonka, MN 55434-USA FDA Establishment Registration Number: 2183959 Sterigenics US, Inc. 7775 South Quincy Street Willowbrook, IL 60527 FDA Establishment Registration Number: 1450293
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Summary Preparation Date:	June 29, 2011
Device Common Name:	Surgical Mesh
Device Trade Names:	AMS Elevate® PC Apical and Posterior Prolapse Repair System with IntePro® Lite AMS Elevate® PC Anterior and Apical Prolapse Repair System with IntePro® Lite
Device Classification	Class II, 21 CFR Part 878.3300
Classification Name:	Surgical Mesh, polymeric (OTP); Mesh, surgical, gynecologic, for pelvic organ prolapse transvaginally placed (OTP)

Predicate Device: AMS Elevate Prolapse Repair Systems with PC Coated IntePro Lite (K090713)

Indications for Use:

The indication for use for the AMS Elevate PC Prolapse Repair System has been revised from a general indication to a more specific indication based on the intended use of each mesh kit type. There is no change to the intended use of the device.

Elevate PC Anterior & Apical Repair System

The Elevate PC Anterior & Apical Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

Elevate PC Apical & Posterior Repair System

The Elevate PC Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

General Device Description
The AMS Elevate PC Prolapse Repair Systems with IntePro Lite consist of a permanently-implanted synthetic mesh assembly, non-implantable needle passers, and other surgical aids that are designed to help place the mesh assembly in the pelvic floor.

The devices is identical to the predicate device AMS Elevate Prolapse Repair System with PC Coated IntePro Lite, with the following exceptions: (1) The anterior needle passer has been modified to add a release mechanism on the handle; and (2) as a result of the anterior needle passer modifications, the connection interface for the tissue fixation elements of the anterior center graft that correspond with the anterior needle passer also changed. The geometry of the internal diameter and the base of the tissue fixation elements changed slightly to accommodate the new shape of the anterior needle tip. There are no changes to the mesh design, shape, size, or material.

Summary of Non-Clinical Testing / Statement of Equivalence:
The components of the AMS Elevate PC Prolapse Repair Systems with IntePro Lite have been subjected to testing which included design verification, biocompatibility, sterilization, packaging, and product performance requirements. The test results conclude the AMS Elevate PC Prolapse Repair Systems with IntePro Lite to be substantially equivalent to the predicate device, AMS Elevate Prolapse Repair Systems with PC Coated IntePro Lite.

American Medical Systems considers the product performance to be significantly equivalent to the predicate device, AMS Elevate Prolapse Repair Systems with PC Coated IntePro Lite.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Mona Inman
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American Medical Systems
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SEP 28 2012

Re: K111118
Trade/Device Name: AMS Elevate® PC Anterior and Apical Prolapse Repair System with IntePro® Lite and AMS Elevate® PC Apical and Posterior Prolapse Repair System with IntePro® Lite
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: June 2, 2011
Received: June 3, 2011

Dear Ms. Inman:

This letter corrects our substantially equivalent letter of July 1, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K111118

Device Name: AMS Elevate® PC Anterior and Apical Prolapse Repair System with IntePro® Lite

Indications for Use:

The Elevate PC Anterior & Apical Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111118